REMARKS

The pending Office Action addresses and rejects claims 1-27.

Rejection Pursuant to 35 U.S.C. §103

Fonger and Purdy

The Examiner rejects claims 1-11, 13, and 15-27 pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent 5,291,896 to Fonger et al. ("Fonger") in view of U.S. Publication 2003/0097082 to Purdy et al. ("Purdy"). The Examiner argues that Fonger teaches the claimed invention except for "(a) the distally disposed pressure sensor embedded in a distal portion of the catheter and (b) the at least one wire having a proximal end mated to an external antenna." The Examiner relies on Purdy to teach these features, arguing that it would have been obvious to modify the device of Fonger in view of Purdy to arrive at the claimed invention. Applicant respectfully disagrees.

Independent claim 1 recites an implantable fluid management device having an elongate catheter, a sensor embedded in a distal portion of the catheter, and at least one wire having a distal end coupled to the sensor and a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor.

It would not have been obvious to modify the device of Fonger to include a distally disposed pressure sensor embedded in a distal portion of the catheter because such a modification would change the principle operation of the reference. As explained in §2143.01 of the *MPEP*, "[i]f the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). In reversing an obviousness rejection, the *Ratti* court held that the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352. Fonger discloses a chest tube (12) which carries an output probe (14) therein. As shown in Figures 1 and 4 of Fonger, the probe (14) has a

transducing head (22) that *extends* from an open, distal end of the tube (12) and includes tines (52) that facilitate *implantation* of the head (22) in an *exterior* surface (62) of a pulmonary artery or aorta vessel (64). (Fonger column 3, lines 46-49; column 4, lines 50-52). Purdy, on the other hand, discloses a device (90) for navigating a subarachnoid space having a catheter with a detector (94) disposed on a sidewall (92) thereof. Modifying Fonger to include an embedded sensor would require removing the existing transducing head (22) in its entirety and reconfiguring the tube (12) to include a sensor embedded in a sidewall thereof. In addition to this modification amounting to a substantial reconstruction and redesign of the Fonger device, it also ignores the teachings of Fonger and changes the basic principle under which the Fonger construction was designed to operate from detection via *implantation* in an exterior surface of an artery or vessel to detection via *insertion* in an artery or vessel.

Even further, modifying Fonger to include an embedded sensor may render the device unsatisfactory for its intended purpose. As explained above, Fonger teaches *extending* the transducing head (22) from the distal end of the tube (12) and *implanting* the head (22) in an *exterior* surface of an artery or vessel (64) such that the surface of the head (22) is in contact with the vessel (64). Embedding the transducing head (22) in a sidewall of the tube (12) would prohibit the implantation of the head (22) in an exterior surface of the vessel (64) thereby rendering the Fonger device unsatisfactory for its intended purposed.

Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over Fonger and Purdy, taken alone or combined, and represent allowable subject matter.

Independent claim 18 recites an implantable fluid management device having an elongate catheter, a sensor disposed at a distal portion of the catheter, at least one wire extending through the catheter, and a slit extending through an outer wall of the catheter. The at least one wire has a distal end that is coupled to a sensor and a proximal end that is mated to an external antenna.

One having ordinary skill in the art would have no motivation to modify the device of Fonger to include an antenna as taught by Purdy. The strongest rationale for combining references is a

recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP §2144). There is no advantage to modifying the cardiac output probe of Fonger to include an antenna as taught by Purdy because there is no need to remotely communicate with or energize the detector of Fonger. As explained at col. 4, lines 26-32 and 50-55, Fonger discloses a *temporary* cardiac output probe assembly for measuring and monitoring cardiac output during the post-operative recovery period following open heart surgery. Since the Fonger probe is specifically designed for in-hospital use when the patient is under the direct supervision of a physician, there is no need to modify Fonger to include an antenna for remote communication, as taught by Purdy.

Accordingly, independent claim 18, as well as claims 19-27 which depend directly or indirectly therefrom, distinguish over Fonger and Purdy, taken alone or combined, and represent allowable subject matter.

Fonger, Purdy, and Quackenbush

The Examiner rejects claims 12 and 14 pursuant to 35 U.S.C. §103(a) as being obvious over Fonger in view of Purdy further in view of U.S. Patent 5,104,398 to Quackenbush ("Quackenbush"). The Examiner argues that Fonger and Purdy teach the claimed invention except for "the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and wherein the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter." The Examiner relies on Quackenbush to teach these features, arguing that it would have been obvious to modify the devices of Fonger and Purdy in view of Quackenbush to arrive at the claimed invention. Applicant respectfully disagrees.

Claims 12 and 14 depend from independent claim 1. As explained above, one having ordinary skill in the art would have no motivation to combine Fonger and Purdy. Quackenbush does not provide any supplemental motivation because Quackenbush merely discloses a splittable tube. Accordingly, independent claim 1, as well as claims 2-17 which depend directly or indirectly therefrom, distinguish over Fonger, Purdy, and Quackenbush, taken alone or combined, and represent allowable subject matter.

Conclusion

In conclusion, Applicant submits that claims 1-27 are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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